

**DETAILED ACTION**

1. This Office Action is in response to the reply received on 1/10/2011.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Applicant's arguments dated 1/10/2011 have been carefully considered, and the instant rejections have been withdrawn, however a new grounds of rejection is deemed necessary.

***Status of the claims***

2. Claims 26-27, 29-42, 44-50, 52-65, 67-71 are pending in the application.

Claims 26-27, 29-42, 44-50, 52-65, 67-71 are presented for examination on the merits.

***Claim Rejections - 35 USC § 102/103***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 26-27, 30-31, 33-36, 38-40, 41-42, 44, 49-50, 53-65, 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by, in the alternative, under 35 U.S.C. 103(a) as obvious over Bloom et al. (US 6,070,761).

Bloom et al. disclose an apparatus for mixing a substance in a sealed container with a liquid, the container being positioned in a container receptacle, the container receptacle configured to couple with a port assembly to permit liquid to enter the container through the port assembly (cols. 2-5 and 13-17), the apparatus comprising:

a container spiking assembly comprising a movable member adapted to move the container receptacle toward the port assembly (e.g., col. 13, see 88 and 77 of Figure 13);

a container spiking assembly controller in communication with the container spiking assembly for controlling coupling of the container receptacle with the port assembly (e.g., col. 15, see 304 and 77 in Figure 7)

a liquid controller for controlling the flow of the liquid through the port assembly into the container to produce a combined substance and liquid, wherein:

the container spiking assembly controller is configured to control the movement of the movable member of the container spiking assembly to couple the container receptacle with the port assembly while the port assembly is immobilized relative to the container receptacle (e.g., col. 15-16 and Figure 13, e.g., 206 and 118, 77).

In cols. 7-8 an automated medication is described, which refers to Figure 3, the automated medication management system 300 includes a control and

management module 304, and a preparation and delivery module 308. The automated medication management system 300 can also include a data entry device 312 and internal data storage 316. Additionally, a communications interface 320 can be provided for communication to external entities such as, for example, an external database 332, etc. In the illustrated embodiment, preparation and delivery module 308 includes fluid delivery module 88 and cassette 77. Propagation and delivery module 308 provides automated reconstitution and dilution of medications, where required or appropriate. In one embodiment, cassette 77 incorporates one or more pressure conduction chambers, which are operated on by positive and negative pneumatic pressure by fluid delivery module 88 to perform reconstitution, dilution and metering of the medication. Fluid delivery module 88 is controlled by control and management module 304. Control and management module 304 determines the appropriate admixture process to be followed for the subject medication and controls fluid delivery module 88 to reconstitute and/or dilute the medication as determined. Control and management module 304 also controls delivery of the medication to the patient (col. 7).

FIG. 29 is a flowchart illustrating a process relating to a door open request. Sensors exist on each of the two fluid delivery module doors, the outer and the inner door. If the outer door is opened, the instrument displays a message to the clinician of the consequences of proceeding. If the user does not want to continue opening the door, they could close the outer door and continue normal operations. If they do continue and open the inner door the

cassette may be compromised and rendered unusable. As discussed previously, this is a safety feature of the device. When a new cassette is loaded, the instrument senses when the doors are closed, test to verify proper closure, and check if the cassette has been previously compromised.

The cassette 77 according to this embodiment is now described. The cassette is comprised of a mid-body 113 which contains the fluid delivery pathways and seats for the diaphragms and valves. Midbody 113 is ultrasonically welded to the two covers which sandwich the diaphragms, valves and control wheel 110 in an assembly. Spikes 118 are separately molded pieces which are also ultrasonically welded to midbody 113 and inner and outer covers 111. Tubing is bonded to the cassette for both the proximal 117 and distal ports 115 and air input port 116. Standard set components make up the remainder of the administration set.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

6. Claims 29, 32, 37, 52, 67 are rejected under 35 U.S.C. 103(a) as obvious over Bloom et al. (US 6,070,761).

Bloom et al. are relied upon as above.

Bloom et al. do not expressly disclose logic for determining the relative locations of the container receptacle and the port assembly, using input from at least one sensor associated with the container spiking assembly; including a cover lock that prevents the cover from being moved from the closed position while the liquid is being received by the container; comprising a sensor within the

container spiking assembly for detecting the location of the container relative to the port assembly. However, Bloom et al. does teach complete automation of the apparatus for mixing a substance in a sealed container with a liquid, the container being position in a container receptacle (e.g., cols. 13-14), which includes complete automation of the instrument. Furthermore, Bloom et al. do teach sensors/logic to detect and control movement (e.g., Figures 29-30, cols. 21-26, 38-39). One of ordinary skill in the art at the time the invention was made would have been motivated to use logic and sensors to control the positioning of the vials, cover locks and spiking assembly based on the teachings of Bloom et al. for full automation. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success given that such methods were available to Bloom et al. as disclosed by Bloom et al. (e.g., cols. 21-26).

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### ***Claim Objections***

7. Claim 71 is objected to because of the following informalities: claim 71 does not have a period at the end of the claim. Appropriate correction is required.
8. Claims 45-48, 68, 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

9. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCELA M CORDERO GARCIA/  
Primary Examiner, Art Unit 1654

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Fluid within cassette 77 is pumped into vials 85 from mixing chamber 109. The means by which vials 85 are attached to cassette 77 is illustrated in FIG. 9 according to one embodiment. Vial 85 is held by clamp 125, part of a vial-loading mechanism discussed below. Spike 118 has a lumen 119 through which fluids and air may pass into cassette 77. When vial 85 is mounted on spike 118, the sharpened end of spike 118 pierces elastic seal 120 of vial 85 so that lumen 119 is now in contact with contents of vial 85. The elasticity of seal 120 ensures an airtight seal about spike 118. Clamp 125 holds vial 85 stationary during system operation. When vial 85 is not mounted, a protective cap 126 covers spike 118 to maintain sterility and to protect users as illustrated in FIG. 10.

FIGS. 12 and 13 illustrate a vial loading mechanism according to one embodiment of the automated medication management system 300. As would be apparent to one of ordinary skill in the art after reading this description, alternative vial loading mechanisms can be implemented.

(77) In order to connect the vials 85 to the cartridges 77, the membrane seals 120 of vials 85 are pierced. The clinician accomplishes this by inverting each vial 85 and lowering the vial 85 onto the spike 118 so as to pierce seal 120 with spike 118.

(78) With reference to FIGS. 12 and 13, to prevent the clinician from accidentally contacting the spikes 118 and injuring oneself, a vial loading mechanism, indicated generally by the reference numeral 200 can be provided. Vial loading mechanism 200 includes a panel assembly 202. Panel assembly 202 has an upper portion 204 and a recessed portion 206